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U.S. DISTRICT COURT
N.D. OF ALABAMA

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

UNITED STATES OF AMERICA, *et al.*, *ex rel.* BROOKS WALLACE, ROBERT FARLEY and MANUEL FUENTES, *et al.*,	)	
Plaintiffs,	)	2:18-cv-01010-LSC
vs.	)	
EXACTECH, INC.,	)	
Defendant.	)	

MEMORANDUM OF OPINION

This is a *qui tam* action brought by Relators on behalf of the United States, 23 states, and themselves against Defendant Exactech, Inc. ("Exactech"), a medical device manufacturer. Relators accuse Exactech of violating and conspiring to violate the federal False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq.*, and corresponding state FCAs by knowingly causing false claims to be submitted to federal and state healthcare programs for defective knee replacement devices surgically implanted by unsuspecting physicians and by using false statements material to those claims. Relators also allege that Exactech violated the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a7b, and the FCA by paying remuneration to physicians who suspected the defects in order to induce them to continue to buy Exactech products.

Before this Court is Exactech's Motion for Summary Judgment (Doc. 143), Exactech's Motions to Strike (Docs. 152, 156, & 168), and Exactech's Motion to Dismiss (Doc. 161). The motions have been fully briefed and are now ripe for review. For the reasons stated below, Exactech's Motion for Summary Judgment is due to be GRANTED IN PART and DENIED IN PART, Exactech's Motions to Strike are due to be DENIED, and Exactech's Motion to Dismiss is due to be DENIED.

I. BACKGROUND[1]

Exactech manufactures the Optetrak Total Knee Replacement ("TKR") system for use during knee replacement surgeries. The Optetrak TKR system involves implanting into the patient a "tibia tray," a component which is anchored to the patient's tibia and connects to the mechanical knee. A patient's first TKR surgery is called a Primary Knee Replacement or "Primary TKR." If such a patient experiences a problem with the Primary TKR device or procedure, the patient may be required to undergo a revision surgery called a "Revision TKR," which is more

[1] The facts set out in this opinion are gleaned from the parties' submissions of facts claimed to be undisputed, their respective responses to those submissions, and the Court's own examination of the evidentiary record. These are the "facts" for summary judgment purposes only. They may not be the actual facts. *See Cox v. Adm'r U.S. Steel & Carnegie*, 17 F.3d 1386, 1400 (11th Cir. 1994). The Court is not required to identify unreferenced evidence supporting a party's position. As such, review is limited to exhibits and specific portions of the exhibits specifically cited by the parties. *See Chavez v. Sec'y Fla. Dept. of Corr.*, 647 F.3d 1057, 1061 (11th Cir. 2011) ("[D]istrict court judges are not required to ferret out delectable facts buried in a massive record . . . .")

complex and involves a larger, heavier implant. One reason a Primary TKR device fails and requires a revision surgery is when the metal device inserted into the patient's tibia becomes loose and begins to wobble, known as "tibial loosening," causing pain and immobility. Until 2011, Exactech had only two options for tibia trays within their Opetrack product line: (1) the allegedly defective Finned Tibia Tray, used in Primary TKRs, and (2) the "Trapezoid" Tray, used in the revision system.

Relators Brooks Wallace ("Wallace") and Robert Farley ("Farley") became Exactech sales representatives in August 2011 and 2012, respectively. Relator Manuel Fuentes ("Fuentes") is a physician who was employed by Exactech from 2006 to 2011. Wallace and Farley marketed and sold the Finned Tibia Tray to multiple physicians and hospitals in Alabama, including Dr. David Lemak ("Dr. Lemak") in Birmingham. Fuentes was involved in Exactech's internal investigation, described in further detail below, into potential causes of the Finned Tibia Tray's tibial loosening problems.

A. Exactech's Knowledge of Problems with the Finned Tibia Tray

On August 22, 2005, Dr. Wayne Moody ("Dr. Moody") reported revisions of Finned Tibia Trays to Defendant, and then, on July 15, 2006, attended an Optetrak Clinician's Meeting to ask for help from Defendant in improving his

technique. (Docs. 149–10 & 149–11). During the July 15, 2006, meeting, Dr. Moody referenced doing 32 revisions. (Doc. 149–11). Dr. Moody was not the only physician to contend that he had issues with tibial loosening of the Finned Tibia Tray. Dr. William Petty confirmed in his deposition that Dr. McCloud and Dr. Lemak also experienced high failure rates due to tibial loosening. (Doc. 145–3 at 11).

B. Exactech's Investigation and Alleged Cover Up

After receiving reports about Finned Tibia Tray failures, Defendant began holding investigatory committee meetings. (Doc. 145–11 at 24–25). In early 2008, during a meeting attended by Fuentes and leading engineers, product managers, and executives within Exactech, Exactech's Director of Marketing proposed that Exactech issue a recall, pull the Finned Tibia Tray inventory from the market, and replace it with the Trapezoidal Tray. (Doc. 149–34 at 3). At this meeting, Jody Phillips, Exactech's CFO, responded that recalling the Finned Tibia Tray was not an option because it would be too financially detrimental, explaining that Exactech was drowning in Finned Tibia Tray inventory and the company could not afford to absorb the inventory cost. (*Id.*) Phillips stated that if Exactech recalled the Finned Tray, the financial damage to Exactech would be too great and thus disclosure of any kind was not a viable financial option. (*Id.*).

Consequently, Exactech decided to neither issue a recall of the Finned Tibia Tray nor disclose any problems related to the device to the FDA, Centers for Medicare & Medicaid Services, its surgeon customers, their patients, or the Department of Justice. Instead, Exactech hired Dr. Ivan Gradisar ("Dr. Gradisar") to audit patient outcomes regarding the Finned Tibia Tray. (Doc. 145–11 at 66). Dr. Gradisar's audit report concluded that out of 47 patients receiving a TKR revision between January 1, 2007, and March 31, 2008, 12 required revision due to tibial loosening from a failed Finned Tibia Tray implant. (Doc. 149–12 at 11). Thus, roughly 25% of the revisions audited by Dr. gradisar over the 15-month period were attributable to tibial loosening. Dr. Gradisar supplemented his audit report, informing Exactech that two surgeons in his practice, Dr. Phil Lewandowski and Dr. Kenneth Green, had previously performed additional revisions due to tibial loosening in the Finned Tibia Tray. (*Id.* at 5–7).

C. Submission of False Claims

Relators argue that Exactech directly submitted false claims for Finned Tibia Trays to the Veterans Administration. Relators provide, among other information, two specific examples of Finned Tibia Trays that were sold to the VA under a "Firm Fixed Price Federal Contract Award." (Doc. 149–25 and Doc. 149–26). These

examples include the delivery order number, the amount the government paid for the device, and the date on which it paid. (*See id.*)

Relators additionally argue that Exactech caused multiple doctors to submit false claims to Medicare for Finned Tibia Tray implants. In support of their indirect presentment argument, Relators proffer data obtained from Centers for Medicare and Medicaid Services ("CMS") which identifies thousands of Exactech Finned Tibia Tray TKAs, claims made by hospitals/medical providers and surgeons for Exactech Finned Tibia Tray TKAs, and the reimbursement paid by CMS for each. (*See* Doc. 149–24). Relators point to UB-04s produced by various hospitals which demonstrate Exactech patients who received the Finned Tibia Trays and were reimbursed by Medicare. (Doc. 149–27).

D. Kickbacks to Dr. Lemak

In 2014, Dr. Lemak saw multiple patients with tibial loosening problems following their Primary TKRs with the Finned Tibia Tray. By late 2017, Dr. Lemak had to perform 55 revision surgeries on patients who had been implanted with the Finned Tibia Tray. At various points spanning from 2014 through 2017, Dr. Lemak expressed to Exactech his dissatisfaction with the extent of the tibial loosenings and his concern that there was a problem with the Finned Tibia Tray. At one point, Dr. Lemak expressed that he was likely going to change devices. After this, Exactech

offered Dr. Lemak a consultant agreement through their newly created sports medicine department. (Doc. 149–4 at 22). However, once Dr. Lemak stopped using Exactech's Finned Tibia Tray, Exactech stopped discussing the consulting agreement with Dr. Lemak. (*Id.* at 23).

II. STANDARD OF REVIEW

A. Subject Matter Jurisdiction

Federal courts are courts of limited jurisdiction, with the power to hear only cases authorized by the Constitution or by statute. *Kokkonen v. Guardian Life Ins. Co. of Am.,* 511 U.S. 375, 377, 114 S.Ct. 1673, 1675 (1994). Under Federal Rule of Civil Procedure 12(b)(1), a party may move the court to dismiss a case if the court lacks jurisdiction over the subject matter of the case. Even when a party does not assert a jurisdictional challenge, "a federal court is obligated to inquire into subject matter jurisdiction *sua sponte* whenever it may be lacking." *Bochese v. Town of Ponce Inlet,* 405 F.3d 964, 975 (11th Cir.2005). Simply put, a federal court is powerless to act beyond its constitutional or statutory grant of subject-matter jurisdiction. *Smith v. GTE Corp.,* 236 F.3d 1292, 1299 (11th Cir.2001). Regardless of how the issue came before the court, a plaintiff, as the party invoking jurisdiction, bears the burden of establishing the court's subject-matter jurisdiction. *Taylor v. Appleton,* 30 F.3d 1365, 1367 (11th Cir.1994).

A challenge to a court's subject matter jurisdiction may come by way of a facial attack or a factual attack. Facial attacks on the complaint require the court merely to look and see if the plaintiff has sufficiently alleged a basis of subject matter jurisdiction, and the allegations in his complaint are taken as true for the purposes of the motion. Factual attacks, on the other hand, challenge the existence of subject matter jurisdiction in fact, irrespective of the pleadings, and matters outside the pleadings, such as testimony and affidavits, are considered. *Garcia v. Copenhaver, Bell & Assocs., M.D.s,* 104 F.3d 1256, 1261 (11th Cir.1997) (citations omitted).

B. Motions to Strike

Fed.R.Civ.P. 26(a) and (e) require parties to disclose all bases of their experts' opinions and to supplement timely their expert disclosures upon discovery of an omission or as required by court order. Fed.R.Civ.P. 37(c)(1) states that when "a party fails to provide information or identify a witness as required by [Fed.R.Civ.P.] 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless." Thus, Rule 37 allows the district court to exclude a witness as a sanction for a Rule 26 violation. "The burden of establishing that a failure to

disclose was substantially justified or harmless rests on the nondisclosing party." *Leathers v. Pfizer, Inc.,* 233 F.R.D. 687, 697 (N.D.Ga.2006).

C. Summary Judgment

Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact[2] and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A dispute is genuine if "the record taken as a whole could lead a rational trier of fact to find for the nonmoving party." *Hickson Corp. v. N. Crossarm Co.*, 357 F.3d 1256, 1260 (11th Cir. 2004). A genuine dispute as to a material fact exists "if the nonmoving party has produced evidence such that a reasonable factfinder could return a verdict in its favor." *Greenberg v. BellSouth Telecomms., Inc.*, 498 F.3d 1258, 1263 (11th Cir. 2007) (per curiam) (quoting *Waddell v. Valley Forge Dental Assocs.*, 276 F.3d 1275, 1279 (11th Cir. 2001)). The trial judge should not weigh the evidence but should determine whether there are any genuine issues of fact that should be resolved at trial. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986).

In considering a motion for summary judgment, trial courts must give deference to the nonmoving party by "view[ing] the materials presented and all

[2] A material fact is one that "might affect the outcome of the case." *Urquilla-Diaz v. Kaplan Univ.*, 780 F.3d 1039, 1050 (11th Cir. 2015).

factual inferences in the light most favorable to the nonmoving party." *Animal Legal Def. Fund v. U.S. Dep't of Agric.*, 789 F.3d 1206, 1213–14 (11th Cir. 2015) (citing *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 157 (1970)). However, "unsubstantiated assertions alone are not enough to withstand a motion for summary judgment." *Rollins v. TechSouth, Inc.*, 833 F.2d 1525, 1529 (11th Cir. 1987). Conclusory allegations and a "mere scintilla of evidence in support of the nonmoving party will not suffice to overcome a motion for summary judgment." *Melton v. Abston*, 841 F.3d 1207, 1219 (11th Cir. 2016) (per curiam) (quoting *Young v. City of Palm Bay*, 358 F.3d 859, 860 (11th Cir. 2004)). In making a motion for summary judgment, "the moving party has the burden of either negating an essential element of the nonmoving party's case or showing that there is no evidence to prove a fact necessary to the nonmoving party's case." *McGee v. Sentinel Offender Servs., LLC*, 719 F.3d 1236, 1242 (11th Cir. 2013) (per curiam). Although the trial courts must use caution when granting motions for summary judgment, "[s]ummary judgment procedure is properly regarded not as a disfavored procedural shortcut, but rather as an integral part of the Federal Rules as a whole." *Celotex Corp. v. Catrett*, 477 U.S. 317, 327 (1986).

III. DISCUSSION

A. Exactech's Motion to Dismiss

Exactech argues that Relators' claims are due to be dismissed because they are "barred by the FCA's public disclosure bar, 31. U.S.C. § 3730(e)(4), and thus, subject-matter jurisdiction is lacking under Rule 12(h)(3)." (Doc. 162 at 1).

The FCA prohibits fraud against government programs. *U.S. ex rel. Osheroff v. Humana Inc.*, 776 F.3d 805, 809 (11th Cir. 2015). Section 3730 of the act allows either the United States government or private citizens to file civil lawsuits to enforce the FCA, but it bars private qui tam suits based on publicly disclosed information. *Id.* In 2010, Congress amended the FCA's public disclosure bar as part of the Patient Protection and Affordable Care Act ("PPACA"), Pub.L. No. 111–148, 124 Stat. 119 (2010). *Id.* Before 2010, the FCA's public disclosure bar provided that "[n]o court shall have jurisdiction" over an action based on publicly disclosed allegations or transactions. 31 U.S.C. § 3730(e)(4) (2006). The PPACA amended this section, which now provides that a "court shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed" in certain enumerated sources. 31 U.S.C. § 3730(e)(4) (2012). The Eleventh Circuit held that

"the amended § 3730(e)(4) creates grounds for dismissal for failure to state a claim rather than for lack of jurisdiction." *Osheroff*, 776 F.3d at 810.

The parties dispute whether the amended version of § 3730(e)(4) applies. The Relators argue that "the pre-PPACA statute which analyzed the Public Disclosure Rule as an issue of subject matter jurisdiction would only apply to false claims caused to be presented by Exactech prior to March 23, 2010." (Doc. 169 at 3). Exactech cites to *Osheroff* to argue that the pre-amendment version of § 3730(e)(4) applies when the "conduct alleged to have occurred" predates the amendment of § 3730(e)(4). (Doc. 171 at 6). If the prior version of § 3730(e)(4) applies to this case, then the public disclosure bar is jurisdictional, and this Court must determine whether subject matter jurisdiction exists. If the amended version of § 3730(e)(4) applies, then Exactech may have waived its right to assert the public disclosure bar under 12(b)(6). *See* Fed R. Civ. Pro. 12(h)(1). However, the Court need not decide which version of § 3730(e)(4) applies, because either way, Exactech's Motion to Dismiss (Doc. 161) is due to be DENIED because the public disclosure bar does not apply in this case. *See* § 3730(e)(4)(A).

The Eleventh Circuit applies a three-part test, to determine whether the FCA's public-disclosure bar applies: "(1) have the allegations made by the plaintiff been publicly disclosed; (2) if so, is the disclosed information the basis of the

plaintiff's suit; and (3) if yes, is the plaintiff an 'original source' of that information." *Osheroff*, 776 F.3d at 812 (quoting *Cooper v. Blue Cross Blue Shield of Florida, Inc.*, 19 F.3d 562, 565 n.4 (11th Cir. 1994)). Here, both parties agree that the allegations made by Relators have been publicly disclosed in various lawsuits and the news media. As such, the first prong is satisfied. However, Exactech's motion to dismiss fails on the second prong. The publicly disclosed information is not the basis of the Relators suit. Instead, the opposite is true. The Declaration of Jon Conlin, a Principal and Shareholder at Cory Watson Attorneys, makes clear that Wallace and Farley actually supplied the information that was the basis of previous litigation and is currently the basis of this litigation.[3] (Doc. 169–4). Further, the Declaration of Farley reveals that Fuentes also had "specific, first-hand knowledge" of the underlying information of this suit. (Doc. 169–5). Thus, the publicly disclosed information is not the basis of Wallace, Farley, and Fuentes' suit. Rather, the firsthand knowledge of Wallace, Farley, and Fuentes is the basis of the publicly disclosed information. Accordingly, Exactech's Motion to Dismiss (Doc. 161) is due to DENIED.

[3] As this is a factual attack on this Court's subject matter jurisdiction, the consideration of declarations is proper. *Garcia,* 104 F.3d at 1261.

B. Motions to Strike

Exactech has filed two separate motions to strike. First, Exactech asks this Court not to consider at summary judgment what they assert is the unilateral deposition of Dr. David G. Lemak. (Doc. 152 & Doc. 156). Second, Exactech asks this Court to strike or exclude the future expert reports of Jason Wells and Dr. Valentina Ngai. (Doc. 168).

i. Dr. Lemak

Exactech argues that Relators took Dr. Lemak's deposition without Exactech's presence in violation of Fed. R. Civ. Pro. 30(b). Relators argue that no deposition occurred. Instead, Relators assert that Dr. Lemak gave a sworn statement. The Eleventh Circuit has indicated that statements made under oath in question-and-answer format and given before a court reporter are properly considered on summary judgment. *Bozeman v. Orum*, 422 F.3d 1265, 1267 n. 1 (11th Cir. 2005) (*overruled on other grounds*). Here, for the purposes of summary judgment, the Court finds that Dr. Lemak gave a statement under oath in question-and-answer format. (*See* Doc. 149-4). As such, the Court will simply treat the statement of Dr. Lemak as an affidavit submitted in opposition to summary judgment.[4] Accordingly, Exactech's

[4] The Court recognizes that Exactech will likely seek to prevent Dr. Lemak from testifying at trial. The Court will address any such argument at the appropriate time should it be properly presented.

Motions to Strike (Doc. 152 & Doc. 156) are due to be DENIED.

ii. Wells and Dr. Ngai

Exactech seeks to strike or exclude any future supplemental expert reports filed by Relators as to Jason Wells and Dr. Ngai. As this motion has no bearing on this Court's summary judgment ruling, Exactech's Motion to Strike or Exclude Relators' Experts (Doc. 168) is due to be DENIED with leave to refile at a later time.

C. Motion for Summary Judgment

i. Counts I & II – 31 U.S.C. § 3729(a)(1)(A)

A claim brought under 31 U.S.C. § 3729(a)(1)(A), must sufficiently show "(1) a false or fraudulent claim, (2) which was presented, or caused to be presented, for payment or approval, (3) with the knowledge that the claim was false." *United States ex rel. Phalp v. Lincare Holdings, Inc.*, 857 F.3d 1148, 1154 (11th Cir. 2017) (citing § 3729(a)(1)(A)). A "claim" for purposes of the FCA includes both "direct requests to the Government for payment as well as reimbursement requests made to the recipients of federal funds under federal benefits programs." *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 579 U.S. 176, 194 (2016) (citing § 3729(b)(2)(A)).

Count I involves the latter type of "claim," alleging that Exactech indirectly caused third parties to present false claims for reimbursement to the Medicare and Medicaid programs. Count II, on the other hand, involves the former type of

"claim," by alleging that Exactech directly presented false claims for payment to the Veterans Administration ("VA"). Under both Counts, Relators proceed under what has been coined the "false certification" theory of liability. "Under this theory, FCA liability may arise where a defendant falsely asserts or implies that it has complied with a statutory or regulatory requirement when, in actuality, it has not so complied." *United States v. AseraCare, Inc.*, 938 F.3d 1278, 1284 (11th Cir. 2019) (citing *Escobar*, 136 S. Ct. at 1999). Claims for government payment that make such assertions or implications are false within the meaning of the FCA. *See Carrel v. AIDS Healthcare Found., Inc.*, 898 F.3d 1267, 1272 (11th Cir. 2018). In addition to alleging (1) falsity of the claim, (2) knowledge, and (3) direct or indirect presentment, relators proceeding under the false certification theory must also show that the false certification is *material* to the Government's payment decision. *See Escobar*, 136 S. Ct. at 1996, 2001–02. This materiality requirement ensures that the FCA does not become "an all-purpose antifraud statute," or "a vehicle for punishing garden-variety breaches of contract or regulatory violations." *Id.* at 2003 (citation omitted). According to the Supreme Court, a claimant states a claim under the false certification theory "at least where two conditions are satisfied: first, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance

with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths." *Id.* at 2001. The Court will now consider falsity, presentment, causation, and materiality in turn.

a. Falsity

Liability under the false certification theory is not limited to false statements of compliance with laws that are "express conditions of payment." *Escobar*, 136 S. Ct. at 2001. The Supreme Court refused to adopt a "circumscribed view of what it means for a claim to be false or fraudulent" under a false certification theory. *Id.* at 2002 (quoting *United States v. Sci. Applications Int'l Corp.*, 626 F.3d 1257, 1270 (C.A.D.C. 2010)). Rather, "concerns about fair notice and open-ended liability" are instead "addressed through strict enforcement of the Act's materiality and scienter requirements." *Id.*

To demonstrate that claims submitted by Exactech were false, Relators show problems with various certification statements within claims submitted by healthcare providers to government healthcare programs. By submitting these forms, healthcare providers certify compliance with the laws and regulations governing the provision of healthcare, that the information submitted is neither false nor misleading, and that all items and services billed for are "reasonable and necessary." As will be explained in further detail below, by plausibly showing that Exactech's

Finned Tibia Tray was "misbranded" and not "reasonable and necessary" in violation of governing healthcare laws, Relators sufficiently show that claims for payment of the device were false under the FCA.

1. Misbranded

A "misbranded" medical device may not be sold in the United States. *See* 21 U.S.C § 331. One way a device becomes "misbranded" is if its manufacturer violates the FDA's requirements for reporting adverse events. *Id.* § 352(t). These requirements compel manufacturers, *inter alia*, to investigate each adverse event, evaluate its causes, and furnish particular information to the FDA within 30 days of receiving or otherwise becoming aware of information "from any source" that "reasonably suggests that a device" a manufacturer markets "[m]ay have caused or contributed to a death or serious injury" or "[h]as malfunctioned and . . . would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur." 21 C.F.R. § 803.50. The FDA defines "caused or contributed" to mean

> that a death or serious injury was or may have been attributed to a medical device, or that a medical device was or may have been a factor in a death or serious injury, including events occurring as a result of: (1) Failure, (2) Malfunction, (3) Improper or inadequate design, (4) Manufacture, (5) Labeling, or (6) User error.

Id. § 803.3(c).

Relators argue that Exactech violated these mandatory reporting requirements, thereby rendering the Finned Tibia Tray "misbranded" and not able to be sold in the United States. (*See* Doc. 54 ¶ 101.) Specifically, Relators argue that Exactech was aware of numerous revision surgeries by Dr. Moody, Dr. Hutchins, other surgeon clients of Exactech distributors, and revision surgeries identified by Dr. Gradisar's audit and accompanying report. Because a "Revision TKR" necessitated by tibial loosening qualifies as a "serious injury," *see* 21 C.F.R. § 803.3(w), Relators argue that Exactech was required to submit adverse event reports for each of these revisions. Thus, because Exactech failed to do so, Relators argue that the Finned Tibia Tray became misbranded, making any subsequent claim for payment of the device false.

After receiving reports about Finned Tibia Tray failures, Defendant began holding investigatory committee meetings. (Doc. 145–11 at 24–25). In early 2008, during a meeting attended by Fuentes and leading engineers, product managers, and executives within Exactech, Exactech's Director of Marketing proposed that Exactech issue a recall, pull the Finned Tibia Tray inventory from the market, and replace it with the Trapezoidal Tray. (Doc. 149–34 at 3). At this meeting, Jody Phillips, Exactech's CFO, responded that recalling the Finned Tibia Tray was not an option because it would be too financially detrimental, explaining that Exactech

was drowning in Finned Tibia Tray inventory and the company could not afford to absorb the inventory cost. (*Id.*). Additionally, Jody Phillips, Exactech's CFO, stated that if Exactech recalled the Finned Tray, the financial damage to Exactech would be too great and thus disclosure of any kind was not a viable financial option. (*Id.*).

Consequently, Exactech decided to neither issue a recall of the Finned Tibia Tray nor disclose any problems related to the device to the FDA, Centers for Medicare & Medicaid Services, its surgeon customers, their patients, or the Department of Justice. Instead, Exactech hired Dr. Gradisar to audit patient outcomes regarding the Finned Tibia Tray. (Doc. 145–11 at 66). Dr. Gradisar's audit report stated out of 47 patients receiving a TKR revision between January 1, 2007, and March 31, 2008, 12 required revision due to tibial loosening from a failed Finned Tibia Tray implant. (Doc. 149–12 at 11). Thus, roughly 25% of the revisions in Dr. Gradisar's practice over the 15-month period were attributable to tibial loosening. Dr. Gradisar supplemented his audit report, informing Exactech that two surgeons in his practice (Dr. Phil Lewandowski and Dr. Kenneth Green) had previously performed additional revisions due to tibial loosening in the Finned Tibia Tray. (*Id.* at 5–7). Accordingly, the evidence presented by Relators is sufficient to create a genuine issue of material facts as to whether the Finned Tibia Tray "caused or

contributed" to "serious injuries," namely, hundreds of revision surgeries. *See* 21 C.F.R. § 803.3. To be sure, Dr. Gradisar's audit and report indicated his belief that one of "multiple" causes of the failures was the improper "cement technique" of the implanting surgeons. (Doc. 149–12 at 9). Even if Dr. Gradisar's belief in "multiple" causes was genuine, this information is nonetheless arguably sufficient to trigger a mandatory adverse event report, as an improper cement technique likely qualifies as "user error" within the reporting regulations. *See* 21 C.F.R. § 803.3(c). Although it did comply with its responsibility to investigate the revisions and their causes, Exactech is hard-pressed in arguing that its discoveries did not obligate it to report to the FDA.[5] Viewing the materials presented and all factual inferences in the light most favorable to Relators, *see Animal Legal Def. Fund*, 789 F.3d at 1213–14, Relators have sufficiently shown that Exactech violated its mandatory reporting obligations in violation of healthcare laws,[6] rendering the Finned Tibia Tray misbranded and making any subsequent claim for payment of the device improper.

[5] This is especially true given the accusations that Exactech failed to take action solely for financial reasons.

[6] Relators also claim that Exactech failed to report revision surgeries for Dr. Moody, Dr. Hutchins, Dr. Balcom, and Dr. Dunitz. (Doc. 159 at 27). However, this Court need not address those claims because the failure to report Gradisar's revision surgeries creates a genuine issue of material fact regarding whether the Finned Tibia Tray was misbranded.

2. Reasonable and Necessary

In addition to allegations of misbranding, Relators also argue that the Finned Tibia Tray is not "reasonable and necessary," in violation of Medicare and Medicaid laws. (*See* Doc. 54 ¶ 1). Healthcare laws provide that "no payment may be made . . . for any expenses incurred for items or services . . . which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the function of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A);[7] *see also AseraCare*, 938 F.3d at 1284. An item or service is "reasonable and necessary" if it is "'safe' and 'effective' . . . that is, . . . [if it] has been proven safe and effective based on authoritative evidence, or alternatively, . . . is generally accepted in the medical community as safe and effective for the condition for which it is used." 54 Fed. Reg. 4302-04. Current Good Manufacturing Practice regulations ("cGMPs") "govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use." 21 C.F.R. § 820.1(a)(1). cGMPs are intended to assure that devices are "safe and effective." *Id.* A device that does not

[7] While this statute refers specifically to the Medicare program, most state laws similarly define medical necessity for Medicaid purposes. *See, e.g.*, Florida Administrative Code (Rule 59G-1.010).

comply with cGMPs is considered "adulterated" and cannot be sold in the United States. *See* 21 U.S.C. § 331.

Relators argue that, because 28–35% of Finned Tibia Trays fail within three years of implantation—a failure rate ten times greater than the industry standard, the Finned Tibia Tray is not reasonable and necessary under relevant healthcare laws. (Doc. 159 at 42). According to Relators, this high failure rate is a result of flaws in Exactech's manufacturing and engineering design process that caused the defective device to be materially different than the device originally approved by the FDA. Relators assert that in 1994, "when the Finned Tibia Tray was cleared using the 510K process, the surface roughness specification for the tray was root means square (RMS) 64 and in 2003 Exactech changed the surface roughness specification to a range of RMS 48 to 80.97." (Doc. 159 at 24–25). Relators' expert, Mari Truman, testified that "the surface roughness in the range of RMS or Ra 48 to 80 Raμin (1 to 28 μm) rendered the Exactech cemented Optetrak Finned Tibial Tray implants unreasonably dangerous and defective" and that, "[t]he preferable surface roughness is in the range of 200 μin to 300μin (~ 5 to 7.6μm) or greater." (Doc. 149–17 at 34). Further, Exactech's lead engineer, Laurent Angibuad, admitted Exactech did not routinely measure surface roughness on production parts but only completed a visual comparison of the surface to the Finned Tibia Trays. (*Id.* at 40).

Exactech argues that summary judgment is appropriate because based on Relators' own count, the revision rate is just 0.86%. (Doc. 153 at 7). Exactech further argues that summary judgment is appropriate because no national coverage determination or local coverage determination (NCD or LCD) has taken the step to deem the Finned Tibia Tray not "reasonable and necessary" such that coverage would be denied for a procedure involving the Finned Tibia Tray. (Doc. 144 at 43–45). Simply put, Exactech argues that the Finned Tibia Trays were "safe and effective." However, the declaration of Relators' expert and Exactech's engineer indicates otherwise. As such, the evidence viewed in the light most favorable to Relators, is sufficient to demonstrate that a genuine issue of material fact exists as to whether the Finned Tibia Tray was "reasonable and necessary."

b. Presentment of a false claim

Demonstrating statutory or regulatory noncompliance is insufficient to state an FCA claim absent demonstration that an actual false claim was presented for payment. *United States ex rel. Clausen v. Lab. Corp. of Am.*, 290 F.3d 1301, 1311 (11th Cir. 2002). "Liability under the False Claims Act arises from the submission of a fraudulent claim to the government, not the disregard of government regulations or failure to maintain proper internal policies." *Corsello v. Lincare, Inc.*, 428 F.3d 1008 (11th Cir. 2005). The submission of a false claim is "the sine qua non of a False

Claims Act violation," *Clausen*, 290 F.3d at 1311. As explained in further detail below, Relators have sufficiently shown that Exactech indirectly caused the presentment of false claims to Medicare and Medicaid and directly presented false claims to the VA.

1. Indirect Presentment to the Medicare and Medicaid Programs

In support of their indirect presentment argument, Relators proffer data obtained from Centers for Medicare and Medicaid Services ("CMS") which identifies thousands of Exactech Finned Tibia Tray TKAs, claims made by hospitals/medical providers and surgeons for Exactech Finned Tibia Tray TKAs, and the reimbursement paid by CMS for each. (*See* Doc. 149–24). Further, Relators point to UB-04s produced by various hospitals which demonstrate patients received the Finned Tibia Trays and were reimbursed by Medicare. (Doc. 149–27). Relators' Expert, Jason Wells, determined that at least 1,922 rows of CMS data tie directly to Exactech data for 2010-2018 surgeries performed using Exactech's Optetrak Finned Tibial Tray. (Docs. 149–24 & 181–1). Exactech argues that no evidence exists showing CMS actually paid for any procedure using the Finned Tibial Tray. (Doc. 183–3). While Relators must certainly present evidence of reimbursement by CMS at trial, Relators have produced enough to meet their burden for the purposes of summary judgment. Relators' presented forms and data and the statement of their

expert demonstrate that a genuine issue of material fact exists as to whether a false claim was indirectly presented for payment.

2. Direct Presentment to the VA

Relators have also sufficiently shown that Exactech directly submitted false claims to the VA. Relators provide, among other information, two specific examples of Finned Tibia Trays that were sold to the VA under a "Firm Fixed Price Federal Contract Award." (Doc. 149–25 and Doc. 149–26). These examples include the delivery order number, the amount the government paid for the device, and the date on which it paid. (*See id.*). This specific billing information is sufficient to create a genuine issue of material fact regarding the direct presentment of false claims to the VA.

c. Materiality

When proceeding under the false certification theory, "a misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision in order to be actionable under the False Claims Act." *Escobar*, 136 S. Ct. at 2002. The FCA's materiality element is "rigorous" and "demanding." *Escobar*, 136 S. Ct. at 2004, n.6. The Supreme Court in *Escobar* declined to answer whether § 3729(a)(1)(A)'s judicially-imposed

materiality requirement is derived from § 3729(b)(4)[8] or directly from the common law, but explained that "[u]nder any understanding of the concept, materiality looks to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation." *Escobar*, 136 S. Ct. at 2002 (internal citation and brackets omitted). The Court explained that, under tort law principles, something is material only "if a reasonable man would attach importance to it in determining his choice of action," or "if the defendant knew or had reason to know that the recipient of the representation attaches importance to the specific matter in determining his choice of action." *Id.* at 2002–03 (internal citations and brackets omitted). The Court further explained that "[m]ateriality in contract law is substantially similar." *Id.* at 2003.

The Court then gave a non-exhaustive list of factors relevant to the materiality analysis. *See id.* at 2003–04. Courts should consider whether noncompliance is "minor or insubstantial" and amounts to "garden-variety breaches of contract or regulatory violations." *Id.* at 2003. Additionally, "the Government's decision to expressly identify a provision as a condition of payment is relevant, but not automatically dispositive." *Id.* It is strong evidence that certain requirements are not

[8] Section 3729(b)(4) defines "material," for purposes of § 3729(a)(1)(B) and (G), as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4).

material "if the Government pays a particular claim in full despite its actual knowledge that [those] requirements were violated," or "if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position." *Id.* at 2003–04.

Exactech argues that Relators cannot satisfy the FCA's "rigorous" materiality standard. (Doc. 144 at 55). Relators argue that the device was misbranded based upon Exactech's failure to report adverse advents which goes far beyond any minor or insubstantial noncompliance. (Doc. 159 at 52). As discussed above, a genuine issue of material fact exists as to whether the Finned Tibia Tray was misbranded. If the Finned Tibia Tray was in fact misbranded, then the sale of such device would have been illegal. *See* 21 U.S.C § 331. Thus, a genuine issue of material fact exists as to whether the Government "would have attached importance to the violation[s] in determining whether to pay" for devices that were misbranded and illegal. Moreover, another piece of evidence that speaks to the effect on the likely or actual behavior of the Government is that the Australian government declined to pay for the Finned Tibia Tray upon determining that the Optetrak knee devices had a high failure rate due to tibial loosening. (*See* Doc. 145–38 at 76–77.) This evidence shows that another government, when made aware of the device's high failure rate, chose not to reimburse for claims for the device, demonstrating that

misrepresentations or omissions about the device's failure rate were material to its decision. *See Escobar*, 136 S. Ct. at 2002.

For the foregoing reasons, Relators have sufficiently shown a genuine issue of material fact exists as to whether Exactech's noncompliance with healthcare laws was material to the government's decision to pay for the Finned Tibia Tray.

d. Knowledge

The FCA defines "knowing" and "knowingly" to mean that a person has "actual knowledge of the information," "acts in deliberate ignorance of the truth or falsity of the information," or "acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1). The FCA's scienter requirement, like its materiality requirement, is "rigorous." *Escobar*, 136 S. Ct. at 2002. While § 3729(b)(1) does not require a "specific intent to defraud," relators proceeding under the false certification theory must show that the defendant knew or should have known that its conduct violated regulations or statutes, *see Phalp*, 857 F.3d at 1154–55, and that such violation was material to the government's payment decision, *see United States ex rel. Marsteller v. Tilton*, 880 F.3d 1302, 1312 (11th Cir. 2018).

Relators have sufficiently shown that a genuine issue of material fact exists as to whether Exactech knew the Finned Tibia Tray was defective. On August 22, 2005, Dr. Wayne Moody ("Dr. Moody") reported revisions of Finned Tibia Trays

to Defendant, and then, on July 15, 2006, attended an Optetrak Clinician's Meeting to ask for help from Defendant in improving his technique. (Docs. 149–10 & 149–11). During the July 15, 2006, meeting, Dr. Moody referenced doing 32 revisions. (Doc. 149–11). As a result, Exactech was aware of the issues with the device at least as of this date because Dr. Moody informed Exactech of the high failure rate. Dr. Moody was not the only physician to contend that he had issues with tibial loosening of the Finned Tibia Tray. Dr. William Petty, in his deposition confirmed that Dr. McCloud and Dr. Lemak also experienced high failure rates due to tibial loosening. (Doc. 145–3 at 11). Further, Dr. Gradisar's Report revealed a revision rate of 25% in 2007. (Doc. 149–12). Also, in early 2008, during a meeting attended by Fuentes and leading engineers, product managers, and executives within Exactech, Exactech's Director of Marketing proposed that Exactech issue a recall, pull the Finned Tibia Tray inventory from the market, and replace it with the Trapezoidal Tray. (Doc. 149–34 at 3).

Because Exactech knew of the complaints of high revision rates and arguably had a duty to report these events to the FDA, a jury could conclude Exactech knew or should have known that its conduct violated regulations or statutes. *See Phalp*, 857 F.3d at 1154–55. Thus, Relators have sufficiently shown a genuine issue of material fact exists as to whether Exactech knowingly submitted and caused to be submitted

false claims to federal healthcare programs. Accordingly, summary judgment is due to be DENIED as to Counts I and II.

ii. Count III - 31 U.S.C. § 3729(a)(1)(B)

To prove a claim under § 3729(a)(1)(B), Relators must show that: (1) Exactech made (or caused to be made) a false statement, (2) Exactech knew it to be false, and (3) the statement was material to a false claim. *Phalp*, 857 F.3d at 1154 (citing 31 U.S.C. § 3729(a)(1)(B)).

a. False Statements

Relators have sufficiently shown that a genuine issue of material facts exists as to whether Exactech made or caused to be made multiple false statements. One false statement is Exactech's representations that the Finned Tibia Tray has a superior failure rate. Relators' have shown that the true failure rate of the Finned Tibia Tray could be as high as 25%. (*See* Doc. 149–12 at 11). Yet, Exactech represented that the Optetrak system has a survival rate as high as 99% at five years. (Doc. 149–22). This study by Dr. Raymond P. Robinson focused exclusively on the survival rate of the Optetrak Trapezoid Tibial Tray, a different device. (Doc. 145–38 at 60–61). Exactech used the results of Dr. Robinson's study to claim that the entire Optetrak system had a 99% survival rate, even though no patient in the study received a Finned Tibia Tray. (*See id.*) Exactech's brochure further represented that the Optetrak

system has a 98.6% survival rate at 8.5 years. (Doc. 149–22). These figures were not updated to reflect Dr. Gradisar's findings in his 2008 audit. (Doc. 145–38 at 58–61). The Exactech marketing materials were updated from 2007 through 2017 and continued to provide the same survival rates mentioned above. (*Id.* at 77).

Further, on October 12, 2011, in a meeting at Exactech headquarters, Exactech failed to disclose to Wallace or Dr. Lemak that it had received hundreds of reports of revision surgeries and had concluded that the Finned Tibia Tray suffered from design and/or manufacturing defects. (Doc. 149–9 at 27). Consequently, from August 2011 to April 2014, Dr. David Lemak performed roughly 215 Primary TKR operations using the Optetrak Finned Tray. (Doc. 149–4 at 6). Of those 215 Primary TKR operations, Dr. Lemak had to revise roughly 25%, performing 55 revisions as of July 2017 – all due to tibial loosenings. (*Id.* at 6–7). These conflicting revisions rates, which were distributed to the public, are sufficient to show that a genuine issue of material fact exists as to whether Exactech made or caused to be made a false statement. *See Phalp*, 857 F.3d at 1154.

b. Materiality

For the reasons explained above with respect to Counts I and II, Relators have sufficiently shown that the false statements made, or caused to be made, by Exactech to Relators, surgeons, and the FDA were material to false claims. Although

materiality in Counts I and II was analyzed according to the standard set forth in *Escobar*, the Court concludes that the evidence also satisfies the standard set forth in § 3729(a)(1)(B) for Count III. Thus, Relators have sufficiently shown materiality for Count III under § 3729(a)(1)(B).

c. Knowledge

For the reasons explained above with respect to Counts I and II, Relators have sufficiently shown that Exactech knew or should have known that its conduct violated regulations or statutes and that such violation was material to the Government's payment decision. Thus, Relators have sufficiently shown Exactech's knowledge for Count III under § 3729(a)(1)(B). Accordingly, summary judgment is due to be DENIED as to Count III.

iii. Count IV - Conspiracy Under 31 U.S.C. § 3729(a)(1)(C)

To prove their conspiracy claim, Relators must show (1) an unlawful agreement between the defendants to commit a violation of the FCA; (2) an act performed in furtherance of the conspiracy; and (3) that the United States suffered damages as a result. *Corsello*, 428 F.3d at 1014. A conspiracy rarely can be established by showing "an explicit agreement; most conspiracies are inferred from the behavior of the alleged conspirators[] and from other circumstantial evidence." *City of*

Tuscaloosa v. Harcros Chems., Inc., 148 F.3d 548, 569 (11th Cir. 1998) (citation omitted).

Relators appear to argue that Exactech and Dr. Gradisar conspired to manipulate the audit he performed in violation of the FCA.[9] (Doc. 159 at 60). However, Relators offer no evidence in support of this conclusion. (See *id.*). Thus, this Court will ignore such argument. *Rich v. Dollar*, 841 F.2d 1558, 1565 & n.5 (11th Cir. 1988) (reversing denial of summary judgment where the district court relied on "assertions in the memorandum prepared by [] counsel"); *Smith v. Housing Auth. of City of Prichard*, No. CIVA 05-0519 WSM, 2007 WL 735553, at *6 n.14 (S.D. Ala. 2007) ("These assertions are unaccompanied by citations to the record, and lack support therein. Of course, mere unsupported representations of counsel do not constitute evidence that may be considered on summary judgment." (emphasis added)); *see also* Doc. 52 ("All statements of fact must be supported by specific reference to evidentiary submissions."). To be sure, Fuentes testified in his deposition that Dr. Gradisar "wanted to protect Exactech" and intentionally skewed the results of his audit. (Doc. 145–11 at 66–67). However, Relators can "no longer rest on such 'mere allegations,' but must 'set forth' by affidavit or other evidence

[9] The Court recognizes that evidence of conspiracies between Exactech and other parties may or may not exist. However, Relators focus their entire conspiracy argument on Dr. Gradisar's audit. As such, this Court will also focus solely on Dr. Gradisar's audit.

'specific facts,'" which they have failed to do. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561, 112 S. Ct. 2130, 2137, 119 L. Ed. 2d 351 (1992). Even if Relators had produced evidence that Dr. Gradisar intentionally skewed the results of his audit, Relators have failed to show that it was due to any agreement with Exactech. Accordingly, summary judgment is due to be GRANTED as to Count IV.

iv. Count V – Reverse False Claims Under 31 U.S.C. § 3729(a)(1)(G)

While a claim under § 3729(a)(1)(A) or § 3729(a)(1)(B) creates liability for false claims requesting money from the Government, a "reverse false claim" under 31 U.S.C. § 3729(a)(1)(G) creates liability for conduct that "results in no payment to the government when a payment is obligated." *United States ex rel. Bain v. Ga. Gulf Corp.*, 386 F.3d 648, 653 (5th Cir. 2004). Liability attaches under § 3729(a)(1)(G) when a person "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals . . . an obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(1)(G). An obligation is defined as "an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, *or from the retention of any overpayment*." 31 U.S.C. § 3729(b)(3) (emphasis added). The Patient

Protection and Affordable Care Act ("ACA") defines "overpayment" as "any funds that a person receives or retains under subchapter XVIII [Medicare] or XIX [Medicaid] to which the person . . . is not entitled under such subchapter." 42 U.S.C. § 1320a-7k(d)(4)(B).

As mentioned above, Relators have sufficiently shown that Dr. Lemak and Grandview had claims submitted to Medicare and Medicaid. (*See* Doc. 149–28). Because those reimbursement claims were false, and Exactech had knowledge of their falsity, Dr. Lemak and Grandview were not entitled to those reimbursements, making them "overpayments." See 42 U.S.C. § 1320a-7k(d)(4)(B). And because Dr. Lemak and Grandview have not returned these overpayments, they are obligations for reverse false claim purposes.[10] Additionally, Relators have shown Exactech falsely told surgeons, including Dr. Lemak, that the Finned Tibia Tray was safe and concealed its long history of failures. (Doc. 149–9 at 27). Through such false statements, Exactech prevented surgeons from learning that they had submitted false claims for payment and therefore had an obligation to repay Medicare or Medicaid for the false claims. Accordingly, Relators have sufficiently shown that a

[10] As mentioned below, the jury will not be allowed to double compensate Relators for false claims and reverse false claims based upon the same facts and circumstances.

genuine issue of material fact exists as to whether Exactech knowingly concealed an obligation to return money to the Government. *See* 31 U.S.C. § 3729(a)(1)(G).

Exactech argues that Relators' claim for relief under 31 U.S.C. § 3729(a)(1)(G) must be dismissed because it is "redundant" of their claims under § 3729(a)(1)(A) and § 3729(a)(1)(B). Several courts, including those in the Eleventh Circuit, have found that in order for the concealment of an obligation to be actionable under the reverse false claim provision, the obligation must arise independent of the affirmative false claims that are actionable under the other FCA provisions. *See United States ex rel. Schaengold v. Mem'l Health, Inc.*, No. 4:11-CV-58, 2014 WL 6908856, at *15–21 (S.D. Ga. Dec. 8, 2014); *see also Pencheng Si v. Laogai Research Found.*, 71 F. Supp. 3d 73, 97 (D.D.C. 2014) (rejecting relator's argument that defendants' concealment of their fraudulent activity resulted in reverse false claim liability because "by this logic, just about any traditional false statement or presentment action would give rise to a reverse false claim action; after all, presumably any false statement action under sections 3729(a)(1)(A) or 3729(a)(1)(B) could theoretically trigger an obligation to repay the fraudulently obtained money").

This Court recognizes that Relators' reverse false claims may be redundant. It appears that at least some of the reimbursement claims are the same ones Relators argue establish liability in Counts I and II. However, the Court will allow evidence to

be presented on this issue at trial. If the Court determines based on the evidence presented at trial that Relators are seeking remedies for the same FCA violations, the Court will instruct the jury that they may not return a verdict double compensating Relators. Accordingly, summary judgment is due to be DENIED as to Count V.

v. Count VI – Federal False Claims Based on Anti-Kickback Statute 31 U.S.C. § 3729(a)(1)(A); 42 U.S.C. § 1320a-7b

The Anti–Kickback Statute ("AKS"), 42 U.S.C. § 1320a7b, prohibits "knowingly offering or providing remuneration for the purpose of inducing the recipient to purchase a good or service for which payment may be made under a federal health care program." *United States ex rel. Osheroff v. Humana Inc.*, 776 F.3d 805, 808 (11th Cir. 2015). Under the AKS, "a claim that includes items and services resulting from a violation of [that statute] constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g). To prove their AKS claim, Relators must show that Exactech (1) knowingly and willfully, (2) offered or paid any remuneration to physicians, (3) to induce the physicians to use the Device, (4) in surgeries paid for by Medicare or Medicaid. See U.S. v. Vernon, 723 F.3d 1234, 1252–53 (11th Cir. 2013) (citing 42 U.S.C. §1320a–7b(b)(2)(A)).

For the reasons explained above, Relators have sufficiently shown the falsity, knowledge, and materiality required to establish FCA liability. In addition, the Court

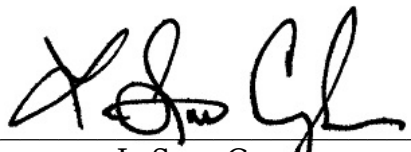
finds that Relators have sufficiently shown a genuine issue of material fact exists as to whether Exactech offered remuneration to Dr. Lemak in order to induce him to purchase Exactech's products or services for which payment may be made under a federal health care program. *See Osheroff*, 776 F.3d at 808. For example, Exactech offered Dr. Lemak a consultant agreement through their newly created sports medicine department only after he complained about the high failure rate he was encountering with the Finned Tibia Tray. (Doc. 149–4 at 22). Further, once Dr. Lemak stopped using Exactech's Finned Tibia Tray, Exactech stopped discussing the consulting agreement with Dr. Lemak. (*Id.* at 23). Viewing the evidence in the light most favorable to Relators, a jury could conclude that the consulting agreement offered to Dr. Lemak was renumeration intended to induce him to continue using Exactech's Finned Tibia Tray. Accordingly, summary judgment is due to be DENIED as to Count VI.

IV. CONCLUSION

For the reasons stated above, Exactech's Motion for Summary Judgment (Doc. 143) is due to be GRANTED IN PART and DENIED IN PART, Exactech's Motions to Strike (Docs. 152, 156, & 168) are due to be DENIED, and Exactech's Motion to Dismiss (Doc. 161) is due to be DENIED. Accordingly, Relators'

conspiracy claim (Count IV) is DISMISSED WITH PREJUDICE. An Order consistent with this Opinion will be entered contemporaneously herewith.

DONE and **ORDERED** on July 25, 2022.



L. Scott Coogler
United States District Judge

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